IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
CHARLOTTE DIVISION
3:08-cv-00361

BETTY LEMONS, Personal Representative of Marie Talley, Deceased	)	
Plaintiff,	)	
v.	)	**ORDER**
NOVARTIS PHARMACEUTICALS CORPORATION,	)	
Defendant.	)	

THE MATTER comes now before the Court upon the Defendant's Motion to Exclude Expert Testimony of the Plaintiff's expert witness, Dr. Suzanne Parisian (D.I. 40), pursuant to the admissibility requirements of Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc*, 509 U.S. 579 (1993) (herein after "*Daubert*"). The Court conducted a hearing on the motion regarding Dr. Parisian's testimony on June 21, 2011. (D.I. 74). The parties subsequently filed additional briefing with the Court regarding the merits of the motion. (D.I. 78, 79). The parties also filed numerous supplemental notices relating to this matter. The motion is currently ripe for review.

I. LEGAL STANDARD

The presentation of scientific and technical knowledge or opinion testimony by a "witness qualified as an expert" is permitted under Rule 702 of the Federal Rules of Evidence where such testimony:

(1) "is based upon sufficient facts or data;"

(2) "is the product of reliable principles and methods;"

(3) results from the reliable application of "principles and methods... to the facts of the case"; and

(4) "will assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. The Supreme Court in *Daubert v. Merrell Dow. Pharm., Inc.,* addressed the admissibility of evidence under Rule 702 and established that trial judges are to act as gatekeepers to "ensure that any and all scientific testimony... is not only relevant but reliable." *Cooper v. Smith & Nephew, Inc.,* 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. 579, 588 (1993)). The trial judge must conduct a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. 579, 592-93.

II. BACKGROUND

Plaintiff's case is part of a Multi District Litigation ("MDL") against Defendant Novartis Pharmaceuticals Corporation ("NPC"). Plaintiff alleges Aredia® and Zometa®, drugs produced by NPC and used in breast cancer patients, caused osteonecrosis of the jaw ("ONJ"). Plaintiff designated Dr. Parisian as an expert for all of the MDL cases, including the one presently before this Court . (D.I. 51, p. 2) (citing *Talley v. Novartis Pharmaceuticals Corp*., No. 3:08-cv-00361-GCM (Apr. 1, 2011)). Defendant filed a Motion to Exclude Dr. Parisian's testimony in its entirety. (D. I. 40, 41). The Court conducted a hearing on the matter on June 21, 2011.

Dr. Parisian earned a medical degree from the University of South Florida in 1978, received a Masters of Biology from the University of Central Florida, and was board certified in Anatomic and Clinical Pathology in 1989. (Expert Report of Dr. Suzanne Parisian, p. 1) (hereinafter "*Report"*). From 1991 to 1995, Dr. Parisian was a Commissioned Officer in the U.S. Public Health

Service, assigned primarily to the Center for Devices and Radiological Health ("CDRH") at the FDA. (*Report*, p. 1). She also had clinical responsibilities at the Armed Forces Institute of Pathology in Washington, DC, and was an FDA Medical Officer in the CDRH, at the FDA. *Id*. at 1. Dr. Parisian was later a Medical Officer and then a Chief Medical Officer at the FDA's Office of Device Evaluation. *Id*. at 3; (D.I. 78, p. 3). Dr. Parisian was also an instructor for the FDA's Staff College training FDA reviewers, she had "primary responsibility for review of marketing applications and labeling" and taught medical officers the process for evaluation and review of the applications. *Id*. at 4. Dr. Parisian also reviewed manufacturing records, product labeling, product complaints and adverse event reports that were submitted to the FDA. *Id*. at 4. Dr. Parisian further testified that at the FDA, she was involved with marketing and draft labeling. *Id*. at 5.

Dr. Parisian founded MD Assist, Inc. in August 1995. *Id*. at 1. MD Assist, Inc. is "a regulatory and medical consulting firm specializing in matters involving the regulation of products by the United States Food and Drug Association." *Id*. at 1. At MD Assist, Dr. Parisian assists individuals, organizations and manufacturers with following FDA requirements, including adverse event reports, labeling, pre and postmarket applications for devices, biologics and drugs, and has consulted regarding changes in requirements for medical device labeling that were proposed by the FDA. *Id*. at 6.

Plaintiff seeks to have Dr. Parisian testify as to four issues: "(a) the role, process, and function of FDA and the responsibilities of pharmaceutical drug sponsors; (b) Novartis' conduct regarding New Drug Application ("NDA") approvals and post-approval of its two intravenous bisposphonates, Aredia® and Zometa®; (c) Novartis' pharmacovigilence efforts, investigation of osteonecrosis of the jaw and interactions with FDA and labeling; and (d) Novartis' communication of ONJ risks to health care providers." (D.I. 78, p. 9). At the hearing, Plaintiff represented to the Court that Dr.

Parisian would only be offered as to opinions "one, two, four, five, and nine." (D.I. 74, p. 15). Dr. Parisian's other opinions will not be analyzed or admitted into evidence either through her expert report or her testimony. Plaintiff's briefing, filed subsequent to the hearing, identifies four issues for Dr. Parisian's testimony that do not match exactly with the opinion testimony Plaintiff identified at the hearing. Therefore, the Court will address the four discrete areas identified in Plaintiff's briefing.

III. OVERVIEW OF THE ARGUMENTS

Defendant seeks to exclude Dr. Parisian's testimony because Defendant argues she is unqualified to offer an opinion on causation as a result of her lack of "specialized knowledge" regarding the medical causation or diagnosis of ONJ. (D.I. 79, p. 9). Defendants emphasize that Dr. Parisian is not an "oncologist, has never prescribed a bisphosphonate . . . and has never treated a patient with ONJ." (D.I. 41, p. 18). Plaintiff and Dr. Parisian have stated that she is not the designated causation expert, to which Defendant responds much of her testimony is "nothing more than thinly veiled causation opinions for which she admittedly lacks expertise." (D.I. 79, p. 9) (citing *In re Trasylol Prods. Liab. Litig.,* 709 F. Supp. 2d 1323, 1331 (S.D. Fla. 2010)). As a result of Dr. Parisian's lack of knowledge and expertise regarding the causation and diagnosis of ONJ, the Defendant requests that the Court preclude Dr. Parisian from testifying about causation and diagnosis of ONJ in patients enrolled in the clinical trials, adverse events reports, or elsewhere. (D.I. 41, p.18).

Defendant contends Dr. Parisian is not qualified to testify regarding the regulation of prescription drugs and proper labeling of medications because she lacks any professional background in this area. (D.I. 41, p. 5). Defendant emphasizes that Dr. Parisian's experience working at the FDA involved medical devices and not prescription drugs. (D.I. 41, pp.5, 17); (D.I. 52, p. 7). Defendant asserts that she has conceded the FDA's regulatory scheme pertaining to drugs

is distinct from that relating to devices. (D.I. 41, p.17) (citing Dep., Vol. 1, 154055). Defendant concludes her complete lack of experience regarding prescription drugs renders her opinions simply speculation, thus failing to satisfy Rule 702. (D.I. 41, pp. 5, 17). The Defendant further objects to Dr. Parisian's testimony regarding labeling because she has failed to draft alternative warning label language for Aredia or Zometa. (D.I. 41, p. 14). Defendant argues that it is well established that testimony of a purported labeling expert is unreliable when the expert has not drafted alternative warning language. (D.I. 41, p. 14). (*citing Bourelle v. Crown Equip. Corp*., 220 F.3d 532, 539 (7th Cir. 2000); *Jaurequi v. Carter Mfg. Co.*, 173 F.3d 1076 (8th Cir. 1999)).

Defendant asserts that Dr. Parisian's opinions about NPC's intent are impermissible. Defendant states "[a]lthough Dr. Parisian admits that she is precluded from testifying about the intent of NPC, FDA, or any other person or organization, she repeatedly opines about NPC's intent and motives." (D.I. 41, p.12) (citing Dep., Vol. 2, 545). Further, "Dr. Parisian also purports to opine that NPC did not act ethically, reasonably, or responsibly." (D.I. 41, p. 12); *see also In re Fosamax Prods. Liab. Litig*., 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (excluding Dr. Parisian's testimony regarding the intent or motives of Merck, its employees, or the FDA). Defendant additionally objects to Dr. Parisian because she allegedly repeats, summarizes, and reads information from other experts without any analysis of her own. (D.I. 41, pp.7-8).

Plaintiff contends Dr. Parisian is qualified to testify as to the FDA's regulatory schemes and the reasonableness of Novartis' conduct based on her years of experience at the FDA. Plaintiff urges the Court to follow the recent decision made in another Aredia®/Zometa® case where the trial judge determined that Dr. Parisian was a suitable expert witness to testify to FDA regulations. (D.I. 78, pp.1-2) (*citing Forman v. Novartis Pharm. Corp.,* No. 09-cv-4678 (E.D.N.Y. March 8, 2011)). In *Forman* the court found Dr. Parisian's testimony was appropriate because "she reached the opinions

expressed in her report by taking the information and applying the relevant FDA regulations and procedures" which "is the same methodology she applied while working at the FDA." *Forman*, No. 09-cv-4678 at *78. The court in *Forman* thus concluded that her methodology was reliable and she was permitted to render opinions regarding "the reasonableness Novartis' conduct in its interactions with the FDA and compliance with FDA regulations," including Novartis' interactions with respect to labels, warnings, and regarding clinical trials. *Id*. at *78.

Dr. Parisian asserts that the methodology employed at the FDA is the same for applying relevant FDA regulations and procedures to devices as to prescription drugs. (D.I. 78, p.5). In addition Plaintiff contends that during Dr. Parisian's tenure at the FDA she worked on "projects involving devices, biologics and drugs." (D.I. 78, p. 5). For example, she was responsible for drug safety concerns regarding ACE inhibitors and reviewed both the drug and device adverse event reports and medical literature. *Id*. at 5. Dr. Parisian has explained that the regulations she used while at the FDA are similar to the specific regulations she contends NPC violated with respect to Aredia® or Zometa®. *Id*. at 5. As a result of her background and work at the FDA, Plaintiff contends Dr. Parisian is qualified as an expert in the "FDA generally and the regulatory requirements relating to the development, testing, marketing and post-market surveillance of prescription drugs such as Aredia® and Zometa®." *Id*. at 7.

The parties disagree as to how the Court should consider Dr. Parisian's previous involvement as an expert witness. Defendant's urge that this Court should exclude Dr. Parisian as many other courts have done. (D.I. 52, pp. 2-6) (*See e.g*. discussion of *In re Trasyol Products Liab. Litig.*, 709 F. Supp.2d 1323 (S.D. Fla. 2010) (Where Dr. Parisian was precluded from offering expert testimony because "she was unable or unwilling to connect her opinions to any valuable regulatory expert analysis and opined on matters that were far beyond her expertise."). Plaintiff asserts in a string of

cases involving Fosamax, which were similar to the Aredia® and Zometa® cases here, courts have allowed parts of Dr. Parisian's testimony. (D.I. 51, p. 2) (citing *In re Fosamax Products Liab. Litig.*, 645 F. Supp.2d 164 (S.D.N.Y. 2009)). The *Fosamax* court "found that Dr. Parisian demonstrated specialized knowledge about the standards applicable to drug manufacturers and that she had applied an appropriate methodology in arriving at her opinions." (D.I. 51, p. 2). Additionally Plaintiff argues this Court should allow Dr. Parisian's testimony because she has been permitted to testify in four other cases involving Aredia® or Zometa®. *See* (D.I. 51, p.2-3) (citing *Forman v. Novartis Pharm. Corp.,* No. 09-cv-4678 (E.D.N.Y. March 8, 2011); *Stevens v. Novartis Pharmaceuticals Corporation,* No. 2010 MT 282 (MT 2010)*; Bessemer v. Novartis Pharmaceuticals Corporation,* No. MID-L-1835-08-T, Superior Court of New Jersey Law Division - Middlesex County*; Fussman Pharmaceutical Corporation,* No. 1:06-CV-149 (M.D.N.C. 2010)).

IV. ANALYSIS

Upon consideration of the arguments regarding the admissibility of Dr. Parisian's testimony as an expert witness for Plaintiff, the Court finds it appropriate to first engage in its function as set forth in *Daubert*: to ensure that any and all scientific testimony or evidence admitted is not only relevant, but also reliable. 509 U.S. 579, 590-91. Here, the Court finds that Dr. Parisian is highly educated, has significant experience with the FDA, and is a seasoned trial expert on the issues presented in this matter. Plaintiff offers Dr. Parisian's testimony on technical topics about which the average layperson has, at best, limited knowledge. Thus, the Court concludes that Dr. Parisian is qualified generally to testify because her testimony is relevant and reliable. Exclusion of her testimony in the entirety would be inappropriate and the Court rejects Defendant's arguments that Dr. Parisian does not possess the requisite expertise or that she will only summarize documents.

Almost every Court that considered Dr. Parisian's testimony in an Aredia® and Zometa® case has found some portion of her testimony to be relevant and reliable and thus found her qualified to testify as a general matter under *Daubert*. *See, e.g., Mahaney ex rel. Kyle v. Novartis Pharm. Corp.,* 1:06-cv-35-TBR, D.I. 151 (W.D. Ky. Sept. 9, 2011) ("Parisian is more qualified to speak on the FDA's role in drug labeling and how its regulations impact pharmaceutical companies like NPC."); *Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 462-69 (E.D.N.Y. 2011) (granting in part, denying in part, and reserving ruling pending a *Daubert* hearing in part with regard to Defendant's motion to exclude Dr. Parisian's testimony); *Fussman v. Novartis Pharm. Corp.,* 1:06-CV-149-JAB-PTS, D.I. 408 (M.D.N.C. Oct. 7, 2010) (denying all *Daubert* motions generally); *Bessemer v. Novartis Pharm. Corp.,* No. MID-L-1835-08 (N.J. Super. Ct. Law Div. Apr. 30, 2010) ("[T]he court shall not exclude the testimony of Dr. Parisian in its entirety."); *Stevens v. Novartis Pharm. Corp.,* DV-08-100 (Mont. 4th Jud. Dist. Ct. Oct 14, 2009) ("Dr. Parisian is qualified based upon her experience as a Medical Officer at the FDA to offer testimony about regulatory requirements relating to the development, testing, marketing and surveillance of prescription drugs."). Defendant cites several cases where Courts considering Dr. Parisians's testimony, in non-Aredia® and Zometa® contexts, have excluded her testimony entirely. *See, e.g. Lopez v. I-Flow, Inc.,* 2011 WL 1897548 (D. Ariz. Jan. 26, 2011); *In re Trasylol Prods. Liab. Litig.,* 709 F. Supp. 2d 1323 (S.D. Fla. 2010). However, the only Aredia® and Zometa® case in which Dr. Parisian, to this Court's knowledge, was not permitted to testify at all was *Hogan v. Novartis Pharms. Corp.*, 2011 WL 1533467 (E.D.N.Y. Apr. 24, 2011).

This Court finds it persuasive that all but one Court, *Hogan*, that considered Dr. Parisian's testimony in an Aredia® or Zometa® case found her testimony to be admissible as a general matter. Furthermore, this Court finds that the *Hogan* Court's reasons for entirely excluding Dr. Parisian's

testimony are not applicable here based on the same reasoning offered by the Court in *Forman v. Novartis Pharm. Corp.,* which also assessed Dr. Parisian's ability to testify in an Aredia® or Zometa® case:

> In *Hogan*, the plaintiff's claims in the complaint were grounded in the state common-law and made no reference to the FDA. In addition, the plaintiff acknowledged that evidence that NPC did not comply with FDA regulations, including the testimony of Dr. Parisian, was mostly necessary to rebut NPC's anticipated defense based on FDA approval of the Zometa label and the lack of FDA action against NPC for the Zometa warnings. However, Judge Cogan noted that, in the parties' joint pre-trial order, NPC had not presented any defense based on the FDA... As a result, Judge Cogan precluded Dr. Parisian's testimony with respect to the FDA, apparently not based on lack of qualifications or improper methodology, but because it was not relevant in the case before him. By contrast, both the Plaintiff and NPC have affirmatively asserted that NPC's compliance, or lack of compliance, with FDA regulations is persuasive evidence of the NPC's [sic] reasonableness and the adequacy of the Aredia and Zometa warnings. Accordingly, absent any representation by the parties to the contrary, the FDA, and NPC's compliance with FDA regulations are issues that are relevant to the instant litigation. Therefore, so is Dr. Parisian's testimony.

2:09-CV-4678-ADS-WDW, D.I. 451 (E.D.N.Y. Jun. 22, 2011). Here, as in *Forman*, the parties appear to agree that Defendant's FDA compliance or non-compliance is an issue, and this Court finds it appropriate to distinguish the instant matter from *Forman*. Accordingly, Defendant's motion to exclude Dr. Parisian's testimony in its entirety is **DENIED** and this Court will address the four issues for Dr. Parisian's testimony that Plaintiff identified in the supplemental briefing.

Plaintiff argues that Dr. Parisian should be allowed to testify as to four specific topics: "(a) the role, process, and function of FDA and the responsibilities of pharmaceutical drug sponsors; (b) Novartis' conduct regarding New Drug Application ("NDA") approvals and post-approval of its two intravenous bisposphonates, Aredia and Zometa; (c) Novartis' pharmacovigilence efforts, investigation of osteonecrosis of the jaw and interactions with FDA and labeling; and (d) Novartis' communication of ONJ risks to health care providers." (D.I. 78, p. 9).

This Court will allow Dr. Parisian's testimony in a limited capacity. Dr. Parisian possesses significant experience with the FDA and its regulatory requirements and procedures regarding new drug application, new drug approval, approved drug monitoring, and labeling of approved pharmaceutical products. The Court finds that Dr. Parisian's testimony will be helpful to the jury as to the first issue identified by the Plaintiff: (a) the role, process, and function of FDA and the responsibilities of pharmaceutical drug sponsors. Certainly, where labeling of a pharmaceutical product is at issue, Dr. Parisian's testimony will assist the trier of fact in understanding the complexity of the FDA's regulatory scheme and the role of a pharmaceutical drug sponsor in complying with that regulatory scheme.

The Court will not allow Dr. Parisian's testimony regarding the second and fourth issues identified by the Plaintiff: (b) Novartis' conduct regarding NDA approvals and post-approval of its two intravenous bisphosphonates, Aredia® and Zometa®; and (d) Novartis' communication of ONJ risks to health care providers. The decision to exclude such testimony is based on the Court's finding that Dr. Parisian does not possess the requisite experience or expertise, as an employee or insider of a pharmaceutical drug sponsor, to opine on the conduct of Novartis.

For the same reason, the Court will not allow Dr. Parisian's testimony, in part, as to the third issue identified by the Plaintiff: (c) Novartis' pharmacovigilence efforts, investigation of osteonecrosis of the jaw and interactions with FDA and labeling. Again, Dr. Parisian does not possess the requisite experience and expertise to opine as to Novartis' (the pharmaceutical drug sponsor) pharmacovigilence efforts or as to Novartis' internal investigation of ONJ. However, Dr. Parisian's experience and expertise with the FDA and its regulatory scheme does render her fit to offer testimony on the issue of Novartis' interactions with the FDA on the subject of labeling. Although Defendant cites two cases, *Bourelle v. Crown Equip Co.,* 220 F.3d 532 (7th Cir. 2000) and

Jaurequi v. Carter Mfg. Co., 173 F.3d 1076 (8th Cir. 1999), in support of its claim that a warnings expert who has not drafted alternative warning language may not testify as to the adequacy of a warning, the Court notes that this precedent is not binding on it and further finds that neither *Bourelle* nor *Jaurequi* requires that Dr. Parisian drafted alternative warning language as a prerequisite to her testimony on the subject. In *Bourelle*, the Seventh Circuit affirmed the exclusion of an expert who never drafted a proposed warning, "render[ing] his opinion akin to 'talking off the cuff,'" and explained that "experts' work is admissible only to the extent it is reasoned, uses the methods of the discipline, and is founded on data. Talking off the cuff - deploying neither data nor analysis - is not acceptable methodology." 220 F.3d at 539. In *Jaurequi*, the Eighth Circuit affirmed the exclusion of two experts who "had [not] created or even designed a warning device which would have been more appropriate, much less tested its effectiveness," but the *Jaurequi* court also found critical the fact that one of the experts never even read the warnings used and was unaware of their content. 173 F.3d at 1084. Here, however, the Court finds that Dr. Parisian's proposed testimony as to labeling is reasoned, based on the context of the warnings, the content of the warnings, and on the consideration of alternative language, and her proposed testimony does not amount to "talking off the cuff." Therefore, the Court will not exclude Dr. Parisian's testimony on the issue of Novartis' interactions with the FDA on the subject of labeling.

Finally, the Court finds it important to note that Defendant seeks exclusion of several discrete areas of Dr. Parisian's testimony as set forth in Defendant's opening brief. (D.I. 41). The Court finds it unnecessary to engage in a detailed analysis of those areas identified by Defendant because this Order draws even more restrictive boundaries on Dr. Parisian's testimony on the basis of the four issues proposed by the Plaintiff. It is clear, for example, that the Court is not allowing Dr.

Parisian to offer testimony regarding NPC's intent, NPC's monitoring of its clinical trials, ghostwriting, legal conclusions, or causation.

V. SUMMARY

Based on the foregoing, Defendant's Motion to Exclude Dr. Parisian's testimony is **DENIED** to the extent that it seeks to exclude Dr. Parisian's testimony in its entirety. However, Defendant's Motion is **GRANTED IN PART AND DENIED IN PART** as to the particular areas of Dr. Parisian's testimony that it seeks to exclude. Dr. Parisian may offer testimony only on the following issues: (1) the role, process, and function of FDA and the responsibilities of pharmaceutical drug sponsors; and (2) Novartis' interactions with the FDA on the subject of labeling.

IT IS SO ORDERED.

Signed: March 21, 2012

Graham C. Mullen
United States District Judge